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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------------------------|----------------------|---------------------|------------------|
| 10/734,548 | 12/12/2003 | Shyam S. Mohapatra | USF-T187XC1 | 4609 |
| 23557 SALIWANCH | 7590 01/30/200 IK LLOYD & SALIW | EXAMINER | | |
| | NAL ASSOCIATION | SHIN, DANA H | | |
| PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 31 DAYS 01 | | 01/30/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | | |
|---|--|--|--|--|--|
| | | 10/734,548 | MOHAPATRA ET AL. | | |
| | Office Action Summary | Examiner | Art Unit | | |
| | | Dana Shin | 1635 | | |
| Period fo | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 07 No | ovember 2006. | | | |
| <i>,</i> — | • — | action is non-final. | | | |
| 3) | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposit | ion of Claims | | | | |
| 5) 6) 7) | Claim(s) 1-13,21 and 22 is/are pending in the aday Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-13,21 and 22 are subject to restriction | vn from consideration. | | | |
| Application Papers | | | | | |
| 10) | The specification is objected to by the Examine The drawing(s) filed on is/are: a) according a constraint may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine | epted or b) objected to by the liderawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | |
| Priority (| under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 2) Notice 3) Infor | nt(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P | ate | | |

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DETAILED ACTION

Election/Restrictions

This Office action is necessitated by plural elections of different inventions and addition of new claims in the reply filed on November 7, 2006. The election requirement set forth in the instant Office action completely supercedes the prior Office action sent to applicants. Applicants are advised to elect accordingly as set forth below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 21-22, drawn to a method of inhibiting an RSV infection in a patient by decreasing the PKC activity comprising administering at least one PKC inhibitor, classified in class 514, subclass 44.

Applicants are further required to elect a single PKC inhibitor from the plurality of inhibitors recited in claim 4, the plurality of inhibitors recited in claim 5, a polynucleotide encoding PKC inhibitor recited in claim 6, and an interfering RNA recited in claim 21. That is, applicants are to elect a single PKC inhibitor to be examined. Note this secondary election requirement is not a species election requirement. See below for reasons. Note also that the election of a single PKC inhibitor will automatically trigger an election of claims to be examined on the merits.

The inventions are distinct, each from the other because of the following reasons:

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The PKC inhibitors claimed in the instant application are patentably distinct and therefore each method comprising different PKC inhibitors are independent inventions. The methods comprising different PKC inhibitors are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are materially different because the PKC inhibitors claimed in claims 4-6 and 21 are structurally and functionally different. For instance, a peptide comprises amino acids; an antisense oligonucleotide comprises a short sequence of nucleic acids; a polynucleotide comprises a long sequence of nucleic acids; an interfering RNA comprises a double-stranded short nucleic acid sequence. Further, the PKC inhibitors recited in claim 4 does not have a common core structure that renders all the PKC inhibitors in claim 4 related. For example, tamoxifen citrate is a nonsterodial antiestrogen which has a structure of triphenylethylene, while melittin is an antimicrobial peptide. Furthermore, the PKC inhibitors as claimed are mutually exclusive as they are structurally and functionally independent, and there is nothing of record to show them to be obvious variants. Furthermore, because the methods comprising different PCK inhibitors are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together would represent a search burden on the examiner.

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Linked Inventions

Claims 1 and 3 link methods of inhibiting an RSV infection comprising administering a PKC inhibitor. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Applicant is reminded to elect a <u>single PKC</u> inhibitor to be examined from the recited PKC inhibitors in the instant application. Applicant is <u>not</u> to elect a single PKC inhibitor from claim 4, a single PKC inhibitor from claim 5 as previously filed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Dana Shin Examiner Art Unit 1635

JANE ZARA, PH.D.